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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/028,884 | 12/21/2001 | Alan Williams | 3441 | 2317 |
| 22886 | 7590 | 05/26/2004 | EXAMINER | |
| AFFYMETRIX, INC ATTN: CHIEF IP COUNSEL, LEGAL DEPT. 3380 CENTRAL EXPRESSWAY SANTA CLARA, CA 95051 | | | ALLEN, MARIANNE P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |
| DATE MAILED: 05/26/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,884

Applicant(s)

WILLIAMS ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19-42 and 44-50 is/are pending in the application.
- 4a) Of the above claim(s) 13-15, 25, 38-40 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16, 17, 19-24, 26-37, 41, 42 and 44-49 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-17, 19-42, 44-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Claims 18 and 43 have been cancelled. Claims 13-15, 25, 38-40, and 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4. Claims 1-12, 16-17, 19-24, 26-37, 41-42, and 44-49 are under consideration.

Information Disclosure Statement

Applicant is again encouraged to file an information disclosure statement.

Claim Rejections - 35 USC § 101

Claims 1-12, 16-17, and 19-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-12 are directed to a method for analysis comprising the steps of aligning sequences, determining quality of a cluster, and modifying the cluster. These steps as written are limited to data manipulation and do not result in a tangible, concrete, and useful result. Note that while the transcript sequences in the cluster are aligned, the claim does not indicate that the cluster has any tangible, concrete, or useful application. As such, these claims are considered to be non-statutory. See MPEP 2106.

Claims 16-24 are directed to a method for designing a nucleic acid probe array comprising aligning sequences, modifying clusters, and selecting probes to design the array. The steps as written are limited to data manipulation and do not result in a tangible, concrete, and useful result. Even as amended, there is no step that designs the array. The final step remains selecting probes intended to be used in designing the array. The intended use is not a positive, active step. Note that while the probes selected are targeted to a cluster the claim does not

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indicate that the cluster has any tangible, concrete, or useful application. As such, these claims are considered to be non-statutory. See MPEP 2106.

Claim Rejections - 35 USC § 112

Claims 1-12, 16-17, 19-24, 26-37, 41-42, and 44-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 and 26 have been amended to include the steps determine the quality of the cluster according to the alignment and modifying the cluster according to the determined quality. Basis is stated to be on page and the originally filed claims. The originally filed claims do not recite these method steps and the disclosure on page 3 is directed to inferring low quality sequence and subclustering or merging clusters. This is not the generic concept present in claims 1 and 26.

In addition, the specification does not appear to disclose that a classification of a cluster as chimeric is a determination of quality of the cluster as implied by the way claims 2-12 and 27-37 are written.

Claims 16 and 41 have been amended to recite selecting probes targeting the at least one modified cluster to design the array. The specification does not appear to contemplate that selection of the probes alone results in designing a nucleic acid probe array.

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Claims 1-12, 16-17, 19-24, 26-37, 41-42, and 44-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 1-12 are directed to a method for analyzing a plurality of transcript sequences in a cluster. The method as written does not provide sufficient positive, active steps to practice the method. The steps are to align sequences, determine quality of the cluster, and modify the cluster. There is no guidance on how quality is determined based upon any alignment. There is no guidance as to how to modify the cluster based upon a particular quality determination. It is not known what type of alignment is considered “good” or “bad” or what type of quality determination requires modification or no modification. It is not known what type of modification to make if the quality determination requires it. It is unclear how classifying a cluster as a chimeric cluster (see for example claim 2) is a determination of quality and how such a classification is used to determine if and how to modify the cluster.

Claims 16-17 and 19-24 are directed to a method for designing a nucleic acid probe array. The method as written does not provide sufficient positive, active steps to practice the method. At least for example, the claim does not have any design steps nor results in a design for a nucleic acid probe array. There is no guidance on how to determine whether the clusters need to be modified. The claims and specification provide no criteria by which such a determination is made and what type of modification to make. The claims and specification provide no criteria

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by which the probes are selected. With respect to how to use, the claims and specification fail to tell how to use the selected probes to design a nucleic acid probe array.

Claims 26-37, 41-42, and 44-49 are directed to a computer readable medium comprising computer executable code to perform a method. As set forth above, the methods as written do not provide sufficient positive, active steps to practice the methods. As such, one would not be able to produce computer executable code to perform the methods as written nor would one know what to do the results of such a method when executed.

Claims 1-12, 16-17, 19-24, 26-37, 41-42, and 44-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 remains incomplete and confusing as it does not provide any criteria by which the quality determination is made. In addition, the metes and bounds of “modifying” is not known. The claim does not make clear what type of modification is to be made, what would demonstrate a need for such modification. See also claim 26.

Claim 7 remains confusing. While claim 2 (upon which it depends) comprises classifying as a chimeric cluster, it does not appear to require identifying multiple clusters or saving such information such that any chimeric cluster could be subclustered. It appears that the **sequences** within the cluster are realigned. Furthermore, claim 2 does not require that a chimeric cluster be found. If no clusters have been classified as chimeric, it is unclear how to proceed in claim 7. See also claim 32.

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Claim 16 is directed to a method of designing a nucleic acid probe array. The final step is selecting probes. Selection of probes does not result in a design for a nucleic acid probe array. The claims are incomplete as the steps recited do not provide the stated goal of the preamble.

Claim 16 is also confusing in reciting “modifying the clusters according to their aligning to the genomic sequence to obtain at least one modified cluster.” This does not set forth the positive, active steps that must be taken. It is not known what the metes and bounds of “modifying” are. The recitation “according to their aligning” does not indicate the criteria by which the need for modification is decided nor the type of modification to be made. See also claim 41.

Applicant appears to be reading limitations or concepts from the specification into the claims. This is improper. The claims are not limited to specific examples in the specification.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

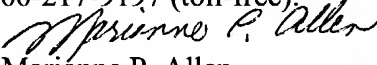
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Marianne P. Allen
Primary Examiner 5/25/04
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